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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,669	06/01/2000	Edward Moacrieff Sellers	064658.0139	4778

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EXAMINER

MELLER, MICHAEL V

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/584,669

Applicant(s)

SELLERS ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 24-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III in Paper No. 8 is acknowledged. The traversal is on the ground(s) that claim 24 is drawn to a kit specifically adapted for use in the method of claim 22. This is not found persuasive since the kit can be used in a materially distinct process such as treating wounds. Applicant has argued this and stated that nothing in the art suggests such a use, but many different compositions can be used for a multitude of reasons. Further, applicant is reminded of the extensive literature search which is involved in biotechnology applications which is not co-extensive. Finally, applicant is reminded that a kit can be a device separating the different components, thus they would not have to be used "contemporaneously" as is required in claim 22 and the combination of the two components of the kit versus the separate components (given at different times) may have different effects on the body than when administered together.

Applicant further argues that claims 4-6 and claim 19 should be examined with the elected invention since claims 4-6 are drawn to a method of using a composition and nicotine as identified for Group III and claim 19 is drawn to a composition comprising a substance which reduces the activity of a CYP2A enzyme and nicotine is likewise adapted for use in a method of using such composition and nicotine as identified for Group III. Claims 4-6 define a method for the treatment or prevention of a

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condition requiring a reduction in the activity of a CYP2A enzyme in an individual in need thereof and there is no indication in the art that the nicotine and the claimed substance in claims 22 and 23 could reduce the activity of a CYP2A enzyme, thus restriction is proper. The composition is not related since it can be used to treat a condition requiring a reduction in the activity of a CYP2A enzyme in an individual which is not indicated by the prior art of record. Thus, the composition is properly restricted. Since the elected group III is a method for enhancing the effectiveness of a nicotine replacement therapy, the claims drawn to a method or composition for the treatment or prevention of a condition requiring a reduction in the activity of a CYP2A enzyme in an individual in need thereof is properly restricted since it is not clear from the art that CYP2A enzyme activity can be reduced.

Applicant's election of the species, methoxsalen is noted. The examiner could not find art on this species, thus the search was extended to the other species.

Therefore, the species pilocarpine was examined.



Claims 1-21 and 24-34 are withdrawn from further consideration by the examiner as being drawn to non-elected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

The disclosure is objected to because of the following informalities: Table 1 comes after Tables 2-5 in the instant specification. This is confusing since the Tables should be in numerical order.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 23 are vague and indefinite since claim 22 recites an improper markush group. The markush group includes, "one or more" and "or both" which is

improper. The markush group should be recited as follows, "a substance selected from the group consisting of a, b, c and d". Further, claim 23 should recite that the "substance inhibits CYP2A6 and is selected from the group consisting of methoxsalen".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viner.

Viner teaches a method for controlling tobacco use and alleviating withdrawal symptoms due to the cessation of tobacco use comprising orally administering to a human desiring to control tobacco use and/or suffering from withdrawal due to cessation of such use an effective amount of a receptor agonist and a stimulant such as nicotine, pilocarpine, and mixtures thereof, see the claims.

Viner does not teach that pilocarpine and nicotine are specifically used together.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use pilocarpine and nicotine together since it is clearly stated in claim 11, that "mixtures thereof" are claimed. Pilocarpine and nicotine are part of the same markush group and since that is the case one of ordinary skill in the art would



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have been motivated to use them together since they are in the same group and the components of the group can be "mixtures thereof".

Further, even though Viner uses a receptor agonist in his composition to be administered, applicant's claims encompass other ingredients besides the nicotine and the pilocarpine since applicant's claims use the term, "comprising".

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Please note that the copy of the International Search Report was inadvertently crossed out on the PTO-1449 and is now included in the PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller
Examiner
Art Unit 1651

MVM
November 19, 2001